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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS' SECOND AMENDED
MOTION AND INCORPORATED
MEMORANDUM TO SEAL**

(Assigned to the Honorable David G.
Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively
“Bard”) hereby submit this Second Amended Motion to Seal and Memorandum relating to
documents filed in support of its Motion for Summary Judgment Regarding Preemption.
Since filing its original filing of its Motion to Seal (Dkt. 5396 & Dkt. 5401), Bard and the
plaintiffs have met and conferred about many of the documents at issue. Bard has now
filed unsealed a large number of the documents previously lodged conditionally under

1 seal. (See, Dkt. 7329).¹ Additionally, Bard has redacted the remaining documents so that
 2 only the trade secrets and confidential information as described in the Declaration of
 3 Robert Carr attached hereto as Exhibit 1 and the Declaration of Elizabeth C. Helm
 4 attached hereto as Exhibit 2 and filed them in redacted form. (See, Dkt. 7330). The
 5 redactions in the documents filed with the Court are limited to Bard's trade secrets and
 6 confidential commercial information and are consistent with the exemptions to the
 7 Freedom of Information Act. (Carr Decl 10,11.) Protecting such information from public
 8 disclosure and from Bard's competitors will prevent Bard from sustaining serious
 9 economic and competitive harm, thereby representing a compelling reason to protect the
 10 documents' confidentiality. Further, while protecting Bard's confidential information, the
 11 redactions do not impair the public's ability to understand the ruling by the Court on
 12 Bard's Motion for Summary Judgment regarding Preemption. Accordingly, the Court
 13 should grant Bard's Motion to Seal.²

14 The documents at issue now fall into the following categories:

- 15 1. Documents which Bard is no longer seeking to seal and has filed. (Dkt.
 16 7329).
- 17 2. Documents Bard has filed redacted (Dkt. 7330 and 7340):
 - 18 a. Documents redacted exactly as they were produced by the FDA
 19 pursuant to a Freedom of Information Act Request. The plaintiffs do
 20 not challenge these redactions (Carr Decl. 10, and Exhibit A thereto)
 21 and Helm Decl. 5).
 - 22 b. Documents redacted consistent with the exceptions to the Freedom of
 23 Information Act to protect Bard's trade secrets and other confidential
 24 information (Carr Decl. 11 and Exhibit B thereto).

25
 26 ¹ Bard originally filed many documents under seal because they are subject to the
 protection of the Stipulated Protective Order.

27 ² Bard has also redacted the original declarations of Robert Carr and John Van Vleet and
 28 its Statement of Material Facts and filed each of those in redacted form (Dkt. 7343 and
 7345).

c. Documents with minor redactions of emails, phone numbers and shipping account numbers agreed to by the parties. (Helm Decl. 4 and Exhibit A thereto).

d. Documents that contain patient health and medical information (Helm Decl. 6 and Exhibit B thereto).

3. Documents which the parties agree should remain under seal until Bard receives a properly-redacted version from FDA. (Helm Decl. 7 and Exhibit C thereto).

ARGUMENT AND CITATION OF AUTHORITY

A. Compelling Reasons Exist to Seal the Redacted Information

Although the Ninth Circuit recognizes that the public has a “general right to inspect and copy public records and documents, including judicial records and document,” *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006) (quoting *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 & n. 7 (1978)), it also recognizes that the right of public access is not absolute and is overcome for materials that “have traditionally been kept secret for important policy reasons.” *Id.* (quotation omitted).

Such compelling reasons for sealing documents exist, for example, regarding proprietary, trade secret, and technical information about FDA submissions—the same type of information that Bard requests that the Court seal here. For example, in *In re Incretin-Based Therapies Products Liability Litigation*, No. 13MD2453 AJB (MDD), 2015 WL 11658712 (S.D. Cal. Nov. 18, 2015), the Court considered motions to seal related to cross-motions for summary judgment on the affirmative defense of preemption. The court found that compelling reasons existed to grant the motions to seal because the information was “confidential and proprietary information specific to each drug at issue and the development, testing, and regulation of each drug.” *Id.* at *3. The court found that such information “is readily subject to improper use resulting in significant competitive harm if disclosed publicly and available to competitors.” *Id.* Moreover, because the court’s analysis in resolving the underlying motions focused on FDA action, as opposed to

1 an “evaluation or analysis of the specific data considered by the FDA,” disclosing the
 2 information publicly “would shed no light on the judicial process and bears the risk of
 3 causing confusion to the public through the limited disclosure of traditionally confidential
 4 data and regulatory submissions.” *Id.*

5 Similarly, in *Spectrum Pharmaceuticals, Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-
 6 GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014), the court considered documents
 7 submitted in support of Sandoz’s motion for summary judgment. The documents related to
 8 an Abbreviated New Drug Application to the FDA, technical information about the
 9 product, and specific efforts to obtain FDA approval of the Application, including actual
 10 and planned confidential communications with the FDA. *Id.* The court found that
 11 information of this nature could injure the parties’ business, thereby constituting a
 12 compelling reason to grant the motion to seal. *Id.*

13 **B. The Redacted Information Contains Bard’s Trade Secrets and Other**
 14 **Confidential Information**

15 The redacted information that Bard seeks to seal in support of its Motion and
 16 Memorandum in Support of Motion for Summary Judgment Regarding Preemption are
 17 the same type of information that the *In re Incretin-Based Therapies* and *Spectrum*
 18 *Pharmaceuticals* courts sealed at the dispositive motions stage. The redacted information
 19 in Bard’s documents reflect confidential and proprietary information concerning the
 20 design, development, testing (including clinical testing), manufacture, and regulatory
 21 compliance activities concerning Bard IVC Filters; portions of 510(k) submissions, IDE
 22 submissions, and other materials sent to FDA that detail Bard’s product development
 23 activities, proprietary testing, and implementation of various proprietary processes and
 24 procedures; contact reports and e-mail communications, which likewise contain
 25 information regarding Bard’s product development activities, proprietary testing, and
 26 implementation of various proprietary processes and procedures; and communications
 27 from FDA, which frequently contain questions that detail and disclose Bard’s product
 28 development activities, proprietary testing, and implementation of various proprietary

processes and procedure. (Carr Decl. 3, 11). This information redacted in the documents took years for Bard to develop and reflect Bard’s critical and confidential business information. (Carr Decl. 14). Moreover, the information would be of economic value to Bard’s competitors, not just for IVC filters, but also to manufacturers of other medical devices, as the information contained in the documents is not limited to IVC filters. *Id.* Bard invests substantial amounts of money in medical device research, testing, clinical trials, development, design, analysis, regulatory compliance, evaluation, and marketing. *Id.* Thus, if Bard’s competitors obtained these documents, they would have an unfair economic advantage over Bard. *Id.*

Moreover, the categories of redacted information at issue have long been recognized as containing information that requires sealing. *See e.g., Spectrum Pharm., Inc. v. Sandoz Inc.*, No. 2:12-CV-00111-GMN, 2014 WL 4202540, at *2 (D. Nev. Aug. 21, 2014) (sealing among other “proprietary business plans” and “business practices,” “actual and planned confidential communications with the FDA”); *Clark v. Metro. Life Ins. Co.*, 2010 WL 1006823 (D. Nev. Mar. 16, 2010) (sealing “confidential internal business deliberations, organization, and capabilities”); *Citizens Comm’n on Human Rights v. Food & Drug Admin.*, 1993 WL 1610471, *7 (C.D.Cal.1993) (A drug application to FDA “by definition contains trade secret information because it contains significant information about how a...drug product is formulated, chemically composed, manufactured, and quality controlled.”), *aff’d in part & remanded in part on other grounds*, 45 F.3d 1325 (9th Cir.1995). *See also, Bracco Diagnostics, Inc. v. Amersham Health Inc.*, CIV 3-6025FLW, 2007 WL 2085350 (D.N.J. July 18, 2007) (“regulatory correspondence” with the FDA, “cost and profit information,” “unpublished clinical studies,” and “internal analyses on products which are not intended for publication or dissemination”). *See also, Medicis Pharm. Corp. v. Acella Pharm., LLC*, CV 10-1780-PHX-JAT, 2012 WL 2260928 at *2 (D. Ariz. June 15, 2012) (sealing exhibits related to “Medicis’ marketing strategy, Acella’s product formulation,...various emails and deposition transcripts, viscosity test data, sales and marketing information, and various

other documents” because “[m]uch of this information has been previously sealed by the Court, has been designated as confidential by the parties pursuant to the protective order in this case, or could otherwise potentially harm the parties if released publicly because of its confidential and sensitive nature.”).

For each category of information listed above, Bard has continually and successfully made efforts to protect the information from its competitors, in part because it could be used by competitors against Bard. (Carr Decl. 13 & 14). Additionally, Bard maintains the confidentiality of the documents and has always sought a Protective Order or Confidentiality Agreement during the course of civil lawsuits in order to protect their confidential, proprietary and trade secret information. (Carr Decl. 7). Therefore, Bard has taken reasonable efforts to maintain confidentiality of these documents and they should remain confidential.

Finally, Bard invests substantial sums of money in medical device research, testing, development, design, analysis, regulatory compliance, and evaluation of its products and does not make such information public. Thus, there is no doubt that the proprietary information which Bard seeks to protect constitutes an overriding interest warranting protection.

C. The Resulting Prejudice From Public Disclosure Requires This Court’s Protection

As stated above, the proprietary redacted information contains highly confidential and sensitive information about Bard’s design, product development, and testing about the Bard Filters, and allowing unrestricted access to this information would cause real and tangible harm to Bard. *See e.g., In re Eli Lilly & Co., Prozac Products Liability Litigation*, 142 F.R.D. 454, 460 (S.D. Ind. 1992) (holding pharmaceutical company would suffer harm if the manufacturing process it has expended time and money on developing became known to competitors); *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 305 *order clarified*, 153 F.R.D. 614 (N.D. Ill. 1993) (“[D]isclosing Raychem’s product design modification and changes would decrease Raychem’s incentive to invest in safety

1 devices. Raychem's competitors would get free access to information which Raychem has
 2 spent a great deal of time and money producing and protecting").

3 Bard invests considerable sums of money in medical device research, testing,
 4 development, design, analysis, regulatory compliance and evaluation. (Carr Decl. 14).
 5 There is no valid reason for Bard's competitors to obtain the results of Bard's product and
 6 marketing development without having to incur similar expenditures in time and money,
 7 since it would give them an unfair economic advantage. It is well documented that the
 8 current market for pharmaceuticals and medical devices is highly competitive. *See, e.g., In*
 9 *re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653, 659 (D.N.J. 2004) (noting the
 10 pharmaceutical industry is highly competitive and granted protective order). An
 11 inadvertent disclosure, through open court records, of Bard's information to any of its
 12 competitors would certainly injure Bard's interest. This heightened level of
 13 competitiveness in the medical device market warrants protecting Bard's efforts in
 14 developing such precise and valuable medical devices, such as the Bard Filters at issue
 15 here. *See, e.g., In re Gabapentin Patent Litigation*, 312 F. Supp. 2d 653 (holding that
 16 evidence supported finding that good cause existed for continued secrecy of materials).

17 To the contrary, because Bard has now redacted the documents, the public will not
 18 be impaired in its ability to understand the ruling by the Court on Bard's Motion for
 19 Summary Judgment Regarding Preemption.

20 CONCLUSION

21 Therefore, compelling reasons exist for protection of Bard's documents, and the
 22 Court should grant Bard's Motion to Seal for the documents filed redacted. Bard
 23 respectfully requests that the Court enters an Order sealing the redactions in documents
 24 filed redacted in Dkt. 7330 and 7340, and the redactions in Declarations of Robert Carr
 25 and John Van Vleet and the Statement of Material Fact. (Dkt. 7343 and 7345).

1 This 28th day of August, 2017.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 28, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Elizabeth C. Helm
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